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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,833	12/07/2001	Donald J. Buchsbaum	21085.0158U1	7772

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,833	BUCHSBAUM, DONALD J.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7,9,10,12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-7, 9, 10, 12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments and Amendments

1. Claims 1, 2, 4-7, 9, 10, 12 and 13 are pending.

Claims 1 and 13 have been amended.

Claims 1, 2, 4-7, 9, 10, 12 and 13 are examined on the merits with species b.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

3. The rejection of claims 1, 2, 4-7, 9, 10, 12 and 13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicant's amendments.

Claim Rejections - 35 USC § 102

4. The rejection of claims 1, 2, 4, 7, 9, 12 and 13 under 35 U.S.C. 102(b) as being anticipated by Colbern et al. (Journal of Inorganic Biochemistry 77: 117-120, 1999) is withdrawn in light of the amendment to claim 1.

Maintained Rejections

Claim Rejections - 35 USC § 102

5. The rejection of claims 1, 2, 4-7, 9, 10, 12 and 13 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 6,632,979 B2 (effective filing date March 16, 2000) is maintained.

Applicant argues the prior art fails to teach each and every limitation of the claims, see Remarks submitted June 2, 2006, page 5, 2nd paragraph. Applicant points out column 1, lines 8-11 of patent '979 asserting this passage states a HER-2 transgenic mouse tumor model does not respond well to HERCEPTIN®, see 3rd paragraph of page 5, Remarks. Applicant asserts with the amendment to claim 1 to include "in conjunction with radiotherapy therapy" the patent fails to disclose every feature of the claimed compositions and does not anticipate the claims, see Remarks, last paragraph of page 6. These points of view and arguments have been carefully considered, but found unpersuasive.

Foremost, the Examiner has reviewed column 1, lines 8-11 and does not note what Applicant asserts is present in those particular lines.

Applicant's attention is directed to column 26, lines 53-67 wherein the disclosure reads on therapeutic regimens combined with the administration of an anticancer agent, such as HERCEPTIN, as well as one or more chemotherapeutic agents. It is reasonable to regard the radioactive isotopes listed in the bridging paragraphs of columns 13 and 14 as reading on radiation therapy. The disclosure is clear and anticipatory. "[T]he treatment of the present invention involves the combined

administration of an anticancer agent identified herein, and one or more chemotherapeutic agents ..., including co administration of cocktails of different therapeutic agents, optionally along with treatment with anti-ErbB2 antibody, such as HERCEPTIN®.", see column 26, lines 61-67. Consequently, the rejection is maintained.

6. The rejection of claims 1, 2, 4-7, 9, 12 and 13 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2002/0051785 A1 (effective filing date March 20, 2000) is maintained.

Applicant is reminded this is a 102(e) rejection and not a 102(b) rejection as noted by Applicant in the Remarks, see first line of page 7.

Applicant argues publication '785 merely suggests an antibody capable of inhibiting Her-2/neu receptor function and/or a TGF-β family member with a chemotherapeutic agent and/or radiation therapy, see Remarks, pages 7 and 8. And Applicant avers the therapies may be used and not enabling. These arguments and points of view have been carefully considered and found unpersuasive.

Patent publication '785 clearly contemplates the claimed method as noted in the first action on the merits (FAOM) mailed September 9, 2005, page 5, section 6, with particularity the last sentence. Applicant is reminded the prior art's method does not need to be reduced to practice. Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 103

7. The rejection of claims 1, 2, 4-7, 9, 10, 12 and 13 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number 2002/0051785 A1 (effective filing date March 20, 2000), in view of U.S. Patent number 6,632,979 B2 (effective filing date March 16, 2000) is maintained.

Applicant reiterates the standard for invoking rejections under 35 U.S.C. 103(a). Applicant asserts the FAOM is remiss in identifying a suggestion, teaching or motivation that would lead one of ordinary skill in the art to make the leap of logic to steps to arrive at the present invention, see Remarks, page 11. Applicant further argues that prior to Dr. Buchsbaum's work the claimed method was unknown and not known to be useful. These arguments and points of view have been carefully considered, but found unpersuasive.

Applicant's retort regarding Dr. Buchsbaum's work is not presented as scientific evidence therefore moot. These arguments are not the kind of factual evidence required to rebut a *prima facie* case of obviousness. As far as the criteria for making rejections under 35 U.S.C. 103(a) the Examiner has met them. The reasonable expectation of success is listed in both documents. Patent publication '785 teaches additional therapies may be employed in the disclosed methods for inhibiting the growth of mammalian cells, see page 2, section 0012 and page 16, section 0135. And patent '979 provides the disclosed therapeutic regimens combined with disclosed anticancer agents are effective in treatment of cancer, see columns 26 and 27. Moreover, the combination of the antibodies and chemotherapeutic agents has been proven to result

in significant antitumor efficacy, see both documents. For the reasons of record and stated above the rejection is maintained.

8. The rejection of claims 1, 2, 4-7, 9, 10, 12 and 13 under 35 U.S.C. 103(a) as being unpatentable over Colbern et al. (Journal of Inorganic Biochemistry 77: 117-120, 1999), in view of U.S. Patent number 6,632,979 B2 (effective filing date March 16, 2000) is maintained.

Applicant argues Colbern and patent '979 do not disclose or suggest every limitation of the claims, see Remarks, page 13, section 2. This argument is found unpersuasive.

Colbern does teach a method of antitumor activity in metastatic breast cancer patients with the administration of a combination therapy inclusive of STEALTH (pegylated) liposomal (PL) cisplatin or non-liposomal cisplatin and Herceptin, see abstract; page 118, sections 2.3 and 2.5 and Results section beginning on page 118. The combination therapy was given at least 6 weeks and at high doses initially then there was dose reduction, see Figures 1 and 2 on page 119; Figure 3 on page 120; and page 120, column 2, first sentence. Colbern does not teach wherein the tumor is colon or pancreatic cancer and in conjunction with radioisotopes and specific chemotherapeutic agents, irinotecan (CPT-11), paclitaxel, 5-fluorouracil, doxorubicin and specifically gemcitabine. Those deficiencies have been met by patent '979.

And it remains *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention to implement a combined Her-2/neu receptor antibodies and

chemotherapeutic/radioisotope treatment to pancreatic and colon cancer. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in the recited patent and Colbern because of the successful treatment of solid tumors with a range of anti-cancer agents observed in both documents. Moreover, the combination of the antibodies and chemotherapeutic in conjunction with radioisotope agents has been proven to result in significant antitumor efficacy, see both documents, with particularity patent '979, column 26 and 27. The instant rejection is maintained.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
10 August 2006